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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,354	01/17/2006	Martin Beer	DEBE:049US/10501329	8965
33425 7590 11/17/2008 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701				
EXAMINER				
MOSHER, MARY				
ART UNIT		PAPER NUMBER		
1648				
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11/17/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/526,354

**Applicant(s)**

BEER ET AL.

**Examiner**

Mary E. Mosher

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

In response to the amendment filed 8/4/2008, the rejections of claim 9 under 35 USC 112, second paragraph; 35 USC first paragraph, written description; and 102(b) over Neubauer et al; are all withdrawn.

### ***Election/Restrictions***

Claims 1-8, 11 and 12 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/13/2008.

### ***Claim Rejections - 35 USC § 112***

Claim 9 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In response to the amendment filed 8/4/2008, the "virus" part of the previous rejection is withdrawn. However, the rejection involving "preventing or treating a disease" is maintained. Applicant argues that the EHV vector has been shown to express genes in a variety of regions in vivo, and the vector can infect a variety of cell types. Applicant argues that the vector is proposed for human gene therapy or immunization generally, as are other vectors known in the art. The examiner agrees that there are many vectors known in the art that can express foreign genes in vivo and can

induce immune responses *in vivo*, and applicant's EHV would be capable of this also. However, applicant is claiming "a method of treating or preventing a disease", which requires therapeutic benefit. Considering the absence of working examples, the limited success of gene therapy in the prior art (as illustrated by the Phillips review previously cited), the unpredictability of the vaccine art, and the scope of the claimed invention, it is maintained that undue experimentation would be required to enable the claimed treatment and prevention method.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willemse et al US 5674499. Willemse teaches a recombinant EHV-1 with a mutation in the

nonessential gene 15. Willemse explicitly suggests inserting heterologous DNA in the region, such as DNA encoding antigens of equine pathogens as a multivalent vaccine, see for example column 5, lines 10-30, column 7, lines 16-62. Willemse explicitly suggests a dose of  $10^3$  to  $10^8$  TCID, which spans the range recited in the claim. Although Willemse does not teach the ability to transduce primary cells at low multiplicity of infection, this would ability would be intrinsic to EHV-1. Therefore, carrying out the explicit suggestions made by Willemse would result in the invention as claimed. It would have been within the ordinary skill of the art to carry out the suggestions, with reasonable expectation of success. Therefore, the invention as a whole is prima facie obvious, absent unexpected results.

The following additional references are cited as of interest:

Brown et al WO 98/26049 teaches a recombinant EHV-1 with a lacZ gene inserted in gene 71, see ED71 in Figure 1. Brown teaches protection of animals from EHV-1 infection by administration of a dose of  $10^8$  infectious units of the virus, see pages 23-29.

Sondermeijer et al WO 00/08165 teaches a recombinant equine herpesvirus, and teaches suitable doses up to  $10^7$  per animal, see pages 10 and 13.

Markham et al WO 98/27216 teaches that EHV-1 is capable of infecting human cells of different lineages in vitro, see page 4, and explicitly suggests its use as a gene therapy vector for humans.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Mary E. Mosher** whose telephone number is **571-272-0906**. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Bruce Campbell** can be reached on **571-272-0974**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

11/12/08